

REMARKS

Claims 1-9 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection revolves around the initial recitation of the "transducer" in the preamble of the independent claims. The problem has been addressed by having the preamble only recite that the invention is an ultrasonic probe, with the transducer portion of the preamble now recited as the first claim element. Accordingly it is respectfully submitted that Claims 1-9 are now clear and definite.

Claims 1 and 9 were rejected under 35 U.S.C. §102(e) as being anticipated by US Pat. 7,081,113 (Sutton) Amended Claim 1 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon formed of a high performance thermoplastic material, and located completely within the probe in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature. Since the volume compensation balloon is formed of a high performance thermoplastic material, it will not stretch as an elastomeric material will. The balloon can therefore be contained in a very small space inside the probe, which is already crowded with the drive mechanism and signal leads to the transducer. Being a thin-walled balloon, little space is consumed by the balloon material itself. At room temperature the volume compensation balloon is limp with only a small fraction of the fluid of the fluid chamber for which it provides volume compensation. If the temperature of the probe increases the

balloon will begin to fill with fluid and compensate for expansion of the fluid in the transducer chamber.

Sutton does not describe an ultrasound probe at all. It describes a therapeutic probe designed to be inserted into spaces in spinal tissue. A helical balloon 41 on the outside of the probe enables the probe to be screwed into its desired location in the body. See col. 9, lines 3-6. A dogbone shaped balloon 313 projecting from the side of the probe can maintain the position of the probe in its desired location. See col. 6, lines 44-55. The Sutton probe has no transducer and no volume compensation balloon located completely inside the probe, nor is one suggested. The Sutton device has no volume compensation balloon at all. For these reasons it is respectfully submitted that Sutton cannot anticipate amended Claim 1.

Claim 9 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation. As previously mentioned, the Sutton probe has no transducer and no volume compensation balloon located completely inside the probe, nor is one suggested. The Sutton

device has no volume compensation balloon at all. For these reasons it is respectfully submitted that Sutton cannot anticipate amended Claim 1.

Claims 2-5 and 7-9 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. pub. no. 2003/0083653 (Maguire et al.) Maguire et al. describe an inflatable r.f. ablation catheter with a balloon 210 that expands against the walls of a pulmonary vein, for instance, to hold the catheter in place at a region to be ablated. The balloon is filled with an electrically conductive fluid. An electrode 220 inside the balloon is then energized to ablate a circumferential region of the surrounding vessel wall. See paragraph [0175] of Maguire et al.

Amended Claim 2 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon is formed of a non elastomeric thermoplastic material. Maguire et al. does not show or suggest an ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 2 or its dependent Claims 3-5.

Amended Claim 7 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the

transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the non elastomeric thermoplastic material comprises a PET polymer. Maguire et al. does not show or suggest an ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 7 or its dependent Claim 8.

Amended Claim 9 describes an ultrasonic probe comprising a transducer located at a distal end of the probe, the transducer being moved within the chamber to scan an image region outside the probe; a fluid chamber enclosing the transducer within the probe; an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber; and a thin-walled volume compensation balloon located completely within the probe and formed of a high performance thermoplastic material in fluid communication with the fluid chamber, the volume compensation balloon containing a small fraction of the fluid of the fluid chamber at room temperature, wherein the thin-walled balloon exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation. Maguire et al. does not show or suggest an

ultrasound probe, the Maguire et al. catheter has no transducer, it performs no scanning of an image region, and it has no volume compensation balloon located inside the catheter. For these reasons it is respectfully submitted that Maguire et al. cannot anticipate Claim 9.

Claims 10-16 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,882,302 (Driscoll, et al.) Driscoll describes a probe with a rotating transducer member 28 having therapeutic surfaces and an imaging transducer 45. The transducer member 28 is located at the transducer region 30 of the probe which is connected to a reservoir 36. An acoustic membrane 38 made of an inelastic, non-distensible, thin membrane covers the transducer region 30. When the transducer region is held in contact with the body of the patient, the pressure P of the fluid inside is controllably varied to displace the adjacent tissue. This displacement enables elasticity imaging of the underlying tissue. Amended Claim 10 describes an ultrasonic probe for three dimensional imaging comprising a probe body enclosing a fluid chamber; an array transducer movably mounted within the fluid chamber; a drive mechanism coupled to the array transducer to move the array transducer during scanning; an acoustic fluid located within the fluid chamber; and a volume compensation balloon located completely within the probe and in fluidic communication with the fluid chamber, the balloon being formed of a substantially non elastic material and being partially expanded at room temperature. Driscoll does not show or suggest a volume compensation balloon for their fluid-filled probe. To the contrary, they have a rigid reservoir 36 which serves as an additional source of fluid for their transducer region 30. The acoustic membrane 30 serves to transmit displacement pulses to the adjacent tissue when the pressure in the transducer region is varied for elasticity imaging. Furthermore, the acoustic membrane is on the outside

of the transducer region, not completely inside the probe as called for by Claim 10. Driscoll gives no thought to volume compensation at all. For these reasons it is respectfully submitted that Driscoll cannot anticipate Claim 10 or its dependent Claims 11-18.

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Maguire et al. Claim 6 recites that the acoustic fluid comprises silicone oil. Silicone oil provides lubrication of the moving transducer assembly inside the probe and is non-corrosive, in addition to being highly transmissive of ultrasound. Maguire et al. give no consideration to these factors. Maguire et al. does not involve ultrasound or ultrasound transducers at all. Maguire et al. describes an r.f. ablation catheter. In addition, Claim 6 depends from Claim 1, and Maguire et al. does not show or suggest an ultrasound probe, an ultrasound transducer, scanning of an image region with a transducer, and Maguire et al. have no volume compensation balloon. For all of these reasons it is respectfully submitted that Claim 6 is patentable over Maguire et al.

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Driscoll. Claim 17 depends from Claim 10 and, as mentioned above, Driscoll does not show or suggest a volume compensation balloon for their fluid-filled probe. To the contrary, they have a rigid reservoir 36 which serves as an additional source of fluid for their transducer region 30. The transducer region 30 is filled with fluid at all times and is not partially expanded at room temperature as called for by Claim 10. Furthermore, the acoustic membrane of Driscoll is on the outside of the transducer region, not completely inside the probe as called for by Claim 10. Driscoll gives no thought to volume compensation at all. For these reasons it is respectfully submitted that Claim 17 is patentable over Driscoll.

In view of the foregoing amendment and remarks, it is respectfully submitted that Claims 1-9 are now clear and definite, that Claims 1 and 9 are not anticipated by Sutton, that Claims 2-5 and 7-9 are not anticipated by Maguire et al., that Claims 10-16 and 18 are not anticipated by Driscoll, that Claim 6 is patentable over Maguire et al., and that Claim 17 is patentable over Driscoll. Accordingly it is respectfully requested that the rejection of Claims 1-9 under 35 U.S.C. §112, the rejection of Claims 1-5, 7-16 and 18 under 35 U.S.C. §102, and of Claims 6 and 17 under 35 U.S.C. §103 be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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